

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Franciscus Antonius Maria RIJSEWIJK et al.
Serial No. : *Divisional of 09/232,469*
Filed : Herewith
Title : BOVINE POLYNUCLEOTIDE VACCINE FOR
THE INTRADERMAL ROUTE
Group Art Unit : Not Yet Assigned
Examiner : Not Yet Assigned


745 Fifth Avenue
New York, NY 10151

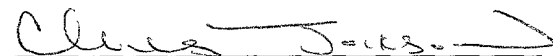
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PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Box PATENT APPLICATION (35 U.S.C. 111)
Washington, D.C. 20231

Sir:

Before examining the above-identified application on the merits, kindly amend
the application as follows:

2007489-0150
58422007

IN THE SPECIFICATION:

Page 1, before line 1, please insert the following new paragraph:

-- RELATED APPLICATIONS

This application is a divisional of application U.S. Patent Serial No. 09/232,469, filed July 15, 1999, now allowed, which in turn is a continuation-in-part of copending International Application PCT/FR97/01322 having an international filing date of 16 July 1997, and designating the U.S. and claiming priority from French application Serial No. 96/09402, filed 16 July 1996. All of the above-mentioned applications, as well as documents cited herein and documents referenced or cited in documents cited herein, are hereby incorporated herein by reference. Vectors of vaccines or immunological compositions of documents cited herein or documents referenced in documents cited herein or portions of such vectors (e.g., one or more or all of regulatory sequences such as DNA for promoter, leader for secretion, terminator), may to the extent practicable with respect to the preferred host and administration route of this application, also be employed in the practice of this invention; and, DNA for vectors of vaccines or immunological compositions herein can be obtained from available sources and knowledge in the art, e.g., GeneBank, such that from this disclosure, no undue experimentation is required to make or use such vectors; see also PCT/IB97/01040, filed July 28, 1997 and designating the U.S., incorporated herein by reference. --

Amend the second paragraph so that it reads as follows:

-- Immunization and vaccination by direct administration of nucleotide sequences encoding an immunogenic protein (called DNA or polynucleotide vaccination) has been described in Patent Application WO-A-90 11092. The protein encoded by the inserted nucleotide sequence is capable of being expressed in the cells and of bringing about the

development of an immune response. (See also U.S. Patent Nos. 5,846,946, 5,620,896, 5,643,578, 5,580,589, 5,589,466, 5,693,622, and 5,703,055; Science, 259:1745-49, 1993; Robinson et al., seminars in IMMUNOLOGY, 9:271-83, 1997; Luke et al., J. Infect. Dis. 175(1):91-97, 1997; Norman et al., Vaccine, 15(8):801-803, 1997; Bourne et al., The Journal of Infectious Disease, 173:800-7, 1996; and, note that generally a plasmid for a vaccine or immunological composition can comprise DNA encoding an antigen operatively linked to regulatory sequences which control expression or expression and secretion of the antigen from a host cell, e.g., a mammalian cell; for instance, from upstream to downstream, DNA for a promoter, DNA for a eukaryotic leader peptide for secretion, DNA for the antigen, and DNA encoding a terminator.) This application envisages the use of naked DNA as well as of DNA contained in liposomes. Preferably, the DNA is introduced into the muscle. The DNA could also be introduced into the skin, into certain organs or into the blood, making it possible for the injection to be carried out in different ways such as the intradermal route, the transcutaneous route, the intravenous route and the like.

IN THE CLAIMS:

Cancel all the claims with prejudice or the intention of creating estoppel and substitute:

--16. A method for inducing an immunological response in a bovine against a bovine pathogen, comprising administering into the epidermis, dermis and/or hypodermis of the bovine an immunogenic composition that comprises a plasmid that contains and expresses *in vivo* in a bovine host skin cell a nucleic acid molecule having a sequence encoding an immunogen of the said bovine pathogen, by a liquid jet intradermal administration apparatus that administers the composition to the bovine: without a needle; and into the epidermis, dermis

and/or hypodermis; wherein the administration of said composite results in the generation of the immunological response in said bovine.

17. An immunogenic composition for inducing in a bovine host an immunological response against a bovine pathogen comprising a plasmid that contains and expresses *in vivo* in a bovine host skin cell a nucleic acid molecule having a sequence encoding an immunogen of the said bovine pathogen, wherein the immunogenic composition is in a liquid jet intradermal administration apparatus that administers the immunogenic composition to the bovine: without a needle ; and into the epidermis, dermis and/or hypodermis.

18. The method of claim 16, wherein the apparatus administers the composition at 1-10 points on the bovine.

19. The method of claim 16, wherein the apparatus administers the composition at 4-6 points on the bovine.

20. The method of claim 16, wherein the apparatus administers the composition at 5 or 6 points on the bovine.

21. The method of claim 16, wherein the apparatus administers the composition at 5 points on the bovine.

22. The immunogenic composition of claim 17, wherein the apparatus administers the composition at 1-10 points on the bovine.

23. The immunogenic composition of claim 17, wherein the apparatus administers the composition at 4-6 points on the bovine.

24. The immunogenic composition of claim 17, wherein the apparatus administers the composition at 5 or 6 points on the bovine.

25. The immunogenic composition of claim 17, wherein the apparatus administers the composition at 5 points on the bovine.

26. The method of claim 16, wherein the bovine pathogen is BRSV.

27. The method of claim 16, wherein the bovine pathogen is IBR.

28. The immunogenic composition of claim 17, wherein the bovine pathogen is BRSV.

29. The immunogenic composition of claim 17, wherein the bovine pathogen is IBR.

30. The method of claim 26, wherein the nucleic acid molecule encodes BRSV G.

31. The method of claim 26, wherein the nucleic acid molecule encodes BRSV F.

32. The method of claim 27, wherein the nucleic acid molecule encodes IBR gB.

33. The immunogenic composition of claim 28, wherein the nucleic acid molecule encodes BRSV G.

34. The immunogenic composition of claim 28, wherein the nucleic acid molecule encodes BRSV F.

35. The immunogenic composition of claim 29, wherein the nucleic acid molecule encodes IBR gB.

36. A method for vaccinating a bovine against a bovine pathogen comprising administering into the epidermis, dermis and/or hypodermis of the bovine a vaccine that comprises a plasmid that contains and expresses *in vivo* in a bovine host skin cell a nucleic acid

molecule having a sequence encoding an immunogen of said bovine pathogen, by a liquid jet intradermal administration apparatus that administers the vaccine to the bovine: without a needle; and into the epidermis, dermis and/or hypodermis, wherein the administration of said vaccine results in the generation of an immunological response in said bovine.

37. A vaccine against a bovine pathogen comprising a plasmid that contains and expresses *in vivo* in a bovine host skin cell a nucleic acid molecule having a sequence encoding an immunogen of said bovine pathogen, wherein the vaccine is in a liquid jet intradermal administration apparatus that administers the vaccine to the bovine: without a needle; and into the epidermis, dermis and/or hypodermis.

38. The method of claim 36, wherein the apparatus administers the composition at 1-10 points on the bovine.

39. The method of claim 36, wherein the apparatus administers the composition at 4-6 points on the bovine.

40. The method of claim 36, wherein the apparatus administers the composition at 5 or 6 points on the bovine.

41. The method of claim 36, wherein the apparatus administers the composition at 5 points on the bovine.

42. The vaccine of claim 37, wherein the apparatus administers the composition at 1-10 points on the bovine.

43. The vaccine of claim 37, wherein the apparatus administers the composition at 4-6 points on the bovine.

44. The vaccine of claim 37, wherein the apparatus administers the composition at 5 or 6 points on the bovine.

45. The vaccine of claim 37, wherein the apparatus administers the composition at 5 or 6 points on the bovine.

46. The method of claim 36, wherein the bovine pathogen is BRSV.

47. The method of claim 36, wherein the bovine pathogen is IBR.

48. The vaccine of claim 37, wherein the bovine pathogen is BRSV.

49. The vaccine of claim 37, wherein the bovine pathogen is IBR.

50. The method of claim 46, wherein the nucleic acid molecule encodes BRSV G.

51. The method of claim 46, wherein the nucleic acid molecule encodes BRSV F.

52. The method of claim 47, wherein the nucleic acid molecule encodes IBR gB.

53. The vaccine of claim 48, wherein the nucleic acid molecule encodes BRSV G.

54. The vaccine of claim 48, wherein the nucleic acid molecule encodes BRSV F.

55. The vaccine of claim 48, wherein the nucleic acid molecules encodes IBR gB.

56. A liquid jet intradermal administration apparatus that administers a composition to an animal: without a needle, and into the epidermis, dermis and/or hypodermis; wherein the apparatus includes an immunogenic composition for inducing in a bovine host an immunological response against a bovine pathogen comprising a plasmid that contains and

expresses *in vivo* in a bovine host skin cell a nucleic acid molecule having a sequence encoding an immunogen of the said bovine pathogen.

57. The apparatus of claim 56, wherein the apparatus administers the composition at 1-10 points on the animal.

58. The apparatus of claim 56, wherein the apparatus administers the composition at 4-6 points on the animal.

59. The apparatus of claim 56, wherein the apparatus administers the composition at 5 or 6 points on the animal.

60. The apparatus of claim 56, wherein the apparatus administers the composition at 5 points on the animal.

61. The apparatus of claim 56, wherein the bovine pathogen is BRSV.

62. The apparatus of claim 56, wherein the bovine pathogen is IBR.

63. The apparatus of claim 56, wherein the bovine pathogen is BRSV.

64. The apparatus of claim 56, wherein the nucleic acid molecule encodes BRSV G.

65. The apparatus of claim 56, wherein the nucleic acid molecule encodes BRSV F.

66. The apparatus of claim 56, wherein the nucleic acid molecule encodes IBR gB.

67. The vaccine of claim 56, wherein the nucleic acid molecule encodes BRSV G. --

REMARKS

This application is a divisional of application U.S. Serial No. 09/232,469.

The amendment to the specification is made to provide a lineage, including proper reference to the International application of which this is a continuation-in-part (see MPEP § 1895.01) and to reference other applications and additional information. These changes were made in the parent application.

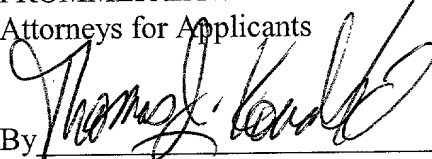
This Amendment cancels all the claims without prejudice or the intention creating estoppel and presents a new set of claims for the examination, which provide for the transdermal vaccinations of bovine by a needleless injector. Support for these new claims is found in the claims which they replace.

It is believed that no additional fee is due. If, however, a fee is due, please charge Deposit Account No. 50-0320.

An early examination on the merits is respectfully requested.

Respectfully submitted,

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APPENDIX SHOWING AMENDMENTS TO THE SPECIFICATION

Amend the second paragraph so that it reads as follows:

Immunization and vaccination by direct administration of nucleotide sequences encoding an immunogenic protein (called DNA or polynucleotide vaccination) has been described in Patent Application WO-A-90 11092. The protein encoded by the inserted nucleotide sequence is capable of being expressed in the cells and of bringing about the development of an immune responses. (See also U.S. Patent Nos. 5,846,946, 5,620,896, 5,643,578, 5,580,589, 5,589,466, 5,693,622, and 5,703,055; Science, 259:1745-49, 1993; Robinson et al., seminars in IMMUNOLOGY, 9:271-83, 1997; Luke et al., J. Infect. Dis. 175(1):91-97, 1997; Norman et al., Vaccine, 15(8):801-803, 1997; Bourne et al., The Journal of Infectious Disease, 173:800-7, 1996; and, note that generally a plasmid for a vaccine or immunological composition can comprise DNA encoding an antigen operatively linked to regulatory sequences which control expression or expression and secretion of the antigen from a host cell, e.g., a mammalian cell; for instance, from upstream to downstream, DNA for a promoter, DNA for a eukaryotic leader peptide for secretion, DNA for the antigen, and DNA encoding a terminator.) This application envisages the use of naked DNA as well as of DNA contained in liposomes. Preferably, the DNA is introduced into the muscle. The DNA could also be introduced into the skin, into certain organs or into the blood, making it possible for the injection to be carried out in different ways such as the intradermal route, the transcutaneous route, the intravenous route and the like.